Otto Bock®

BEST IN FOAM

K083012 4/14

APR - 9 2009

5. 510(k) Summary

[As required by 21 CFR 807.92(c)]

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Date prepared: February 04, 2009

Device Name
Proprietary Name: PapCone®
Common/Usual Name: Cervical Cell Scraper
Classification Name: Cervical Cytological Endocervical Brush

Predicate Devices
Cervex-Brush® (Rovers Medical Devices B.V., K930955)
Puritan Foam Tip Swab Model 2197 (Hardwood Products Company LP, K961934)

Device Description
The PapCone® consists of an axially symmetric polystyrene grip with a round platform carrying a foam cone (PUR Foam B 2240), which is intended to collect exfoliated epithelial cervical cells for analysis by Pap smear methods. Due to its shape, dimension and the porosity of the foam used for PapCone® it is possible to obtain cells from the endocervix and the ectocervix.
The design of the foam prevents distortion of the cells during sampling and transfer. During a gynecological examination the foam cone portion of the PapCone® is inserted for $^2/_3$ into the cervical canal and is rotated two times for collection of cervical cells. The cells are transferred to a glass slide by applying gentle pressure and rotating the PapCone® evenly against the direction of streak on the slide, this allows for a uniform distribution of cells on the slide. To ensure the adequate coverage of the periphery of the transition zone, it is generally recommended to swap the periphery additionally with a second instrument (e.g. PapCone® or a spatula). Transfer these cells to the same glass slide.
The device is offered non sterile.

Intended Use Statement
PapCone® is a medical device intended for the collection of exfoliated cervical cells for analysis by Pap smear methods. The PapCone is not intended for use in pregnant women.

Technological Characteristics and Substantial Equivalence
The Cervex-Brush® consists of a multi-bristled soft plastic broom mounted onto the end of a plastic handle. The Cervex-Brush® is used for the conventional smear as well as for the liquid based cytology.

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The substantial equivalence is given by the shape of the broom and the resulting simultaneous sampling of endo- and ectocervix.

The Puritan Foam Tip Swab Model 2197 consists of a cylindrical polyurethane foam tip bonded to a polystyrene shaft. The device is used for the endocervical sampling. The substantial equivalence is given by the materials and usage of foam as sampling material.

The PapCone® is substantially equivalent in terms of intended use and principles of operation to the Cervex-Brush® and to the Puritan Foam Tip Swab Model 2197 for materials and principles of operation. None of the devices are intended for the use in pregnant women.

Performance testing (bench testing)
The substantial equivalence of the three devices has been shown by a bench test. During this test, the technical function to obtain and to release particles with diameters ranging from 20 µm to 100 µm within a viscous suspension has been compared. The viscosity of this suspension has been comparable to the viscosity of cervical mucus. All three devices have performed within the same range.

Device	Mean value	Standard dev.	Max.	Min.	Spread
Cervex-Brush®	**241**	**54**	377	166	3,89
FT Modell 2197®	**205**	**57**	349	118	4.04
PapCone®	**273**	**50**	378	177	4.06

Clinical performance data
After its legal marketing in Europe PapCone® has been the subject of a clinical performance evaluation (SANDER H. et. al: Sampling devices for cytological examinations, 2007 – see attachment E). PapCone® has been compared to the combination of spatula and brush and to the cotton tip. In this comparison 31,000 smears have been taken and compared. The evaluation of PapCone® concerning the handling (sampling and smear), the time needed for the sampling and the acceptance by the patient has shown a good acceptance of the PapCone® by medical professionals and by the patients. This comparison has shown the following advantages of PapCone®:

- better physician-patient-compliance due to reduced iatrogenic bleeding
- increased representative sampling due to increased number of cells

The statistical detection rate of positive cytological findings was equal for the compared instruments.

Risk management
During the process of development of PapCone® a risk management according to ISO 14791 has been established. The evaluation of the potential risk for the user or the patient has shown no evidence of harmful potential if the device is used according to its instruction for use by medical professionals.

Biocompatibility
The intended contact of PapCone® and the human body is the foam cone (made from B 2240) and the mucosal membrane of the female cervix. Therefore PapCone® is a surface device. The duration of the contact is limited (less than 24 h, approximately less than 1 minute).
The PapCone® has been proven to be physiologically harmless through external testing. ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and delayed type hypersensitivity) testing was performed on the B 2240 foam. The complete PapCone (shaft and foam) was tested in accordance to ISO 10993-5 (Cytotoxicity) and ISO 10993-12 (investigation of extractable organic substance and GC/MS fingerprint).
The results of these tests indicated the patient will have no harmful reactions when using the PapCone®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Otto Bock Pur Life Science GmbH
c/o Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste. 104
NEW BRIGHTON MN 55112-1891

APR - 9 2009

Re: K083012
Trade/Device Name: PapCone®
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: March 23, 2009
Received: March 27, 2009

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

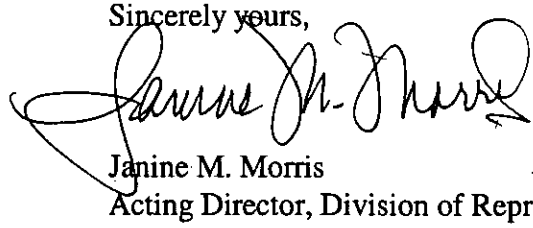
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indication for Use

510(k) Number (if known): K083012

Device Name: PapCone®

Indication for Use:

PapCone® is a medical device intended for the collection of exfoliated cervical cells for analysis by Pap smear methods. The PapCone is not intended for use in pregnant women.

Prescription Use **X** (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083012